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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	88066-5700	6851

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the addition of claim 31, currently claims 1-7, 9-13 and 15-31 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-10, 12-13, 16-20, 22-27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultzer (4,968,302). Schultzer discloses an automatic hypodermic syringe.

Regarding claim 1, 17, 18 and 30, Schluter et al. discloses a jet injector for highspeed injection (see abstract) of a medicament with a cylindrical tube (2), a first and second stopper, wherein the medicament (292) is between the stoppers (29, 22), and once triggered the first stopper pushes the second stopper through a needle (3) creating a fluid path for insertion into the body (Figures 1, 5A).

Regarding claims 2-6, 9-10, 12-13, and 16, Schluter et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel (34) of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A).

The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-27, Schluter et al. discloses an injection system in that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figures 5A-5B). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 5A).

Claim Rejections - 35 USC § 102

Claims 1-6, 9-10, 12-13, 16-20, 22-28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wardlaw et al. (4,258,713).

Regarding claim 1, 17, 18, and 30-31, Wardlaw et al. discloses an injector (see abstract) of a medicament (14) with a cylindrical tube (2), a first and second stopper (10, 12), wherein the medicament is between the stoppers, and once triggered the first stopper pushes the second stopper through a needle (18) creating a fluid path for insertion into the body (Figure 1).

Regarding claims 2-6, 9-10, 12-13, and 16, Wardlaw et al. discloses that the movement of the stoppers compresses the medicament through the needle and second piercable stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1). The lumen of the tube is cylindrical and configured to fire via an injector system to expel the medicament (Figure 1).

Regarding claims 19-20, 22-28, Wardlaw et al. discloses an injection system in that the movement of the stoppers (second stopper with an are that is designed for needle piercing) compresses the medicament through the needle that is fixed upon injection and second piercable stopper (Figure 1). The needle has a bevel of the piercing end and injection end, with the injection end extending beyond the end of the tube (Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 11, 15, 21, and 29 are rejected under 35 U.S.C 103(a) as being unpatentable over Schluter et al. in view of Tanaka et al. (5,865,799). Schluter et al. meets the claim limitations as described above but does not include a third stopper, with a recess, and mixing of insoluble particles.

However, Tanaka et al. teaches a pre-filled syringe. Regarding claim 7, 11, 15 21 and 29, Tanaka et al. discloses a third stopper, and an enlarged portion, that is used to mix particles prior to injection (Figures 1 and 5).

At the time of the invention, it would have been obvious to use the stopper system of Tanaka et al. with the system of Schluter et al. because the addition of a third stopper and enlarged portion allows for different drug combination doses to be injected. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tanaka et al.

Response to Arguments

Applicant's arguments, see remarks, filed 12/27/2006, with respect to claim 28 have been fully considered and are persuasive. The rejection of claim 28 under Wardlaw (4,258,713) has been withdrawn.

Applicant's arguments filed 12/27/2006 have been fully considered but they are not persuasive. Regarding claims 28 and new claim 31, Applicant's representative asserts that the needle of Schluter et al. is not fixed to the distal portion of the tube and that it needs to be moveable to retract. Examiner does not find this argument compelling, the needle of Schluter et al. does not retract and becomes fixed to the second end of the medicament containing tubular lumen after injection and therefore meets the claim limitation.

Additionally, Applicant's representative argues that the injectors cited are not jet injectors. As cited in the previous actions with this Examiner and the prior Examiner,

Applicant's specification does not disclose any evidence to support Applicant's representatives claims of the skilled art at the time of invention, the only mention of "hypodermic or jet injector" in the first filed abstract, there is nothing else that would preclude Examiner's interpretation that the cited references can act as needle assisted jet injectors, and Applicant's specification does not disclose how Applicant's invention differs from the injectors cited. The injectors of Wardlaw and Schulter et al. contain structurally similar elements that meet the claim limitations and are capable of dispersing the medicament as argued by Applicant's representative (not a needle bolus but energized needle injection). Examiner has suggested allowable subject matter (see below) that would overcome the prior art of record.

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

In order to expedite prosecution Examiner recommends the addition of structural limitations drawn to the stopper relationships as shown in Figures 7-9, i.e. limitations drawn to the shape/size of stopper elements (24, 30, 22) to the independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/27/07

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